PATENT SPECIFICATION (11) 1 431 841

1 431 841

(21) Application No. 2043/73 (22) Filed 15 Jan 1973

(23) Complete Specification filed 14 Sep 1973

(44) Complete Specification published 14 Apr 1976

(51) INT CL^2 A61K 31/00

(52) Index at acceptance

A5B 230 23Y 285 28Y 31X 31Y
360 361 362 363 364 365
36X 36Y 402 40Y 413 41Y

(19)

(54) "OPHTHALMIC-NUTRITIONAL PREPARATIONS"

(71) I, STANLEY CHARLES EVANS of 21, ALEXANDRA ROAD, LOWESTOFT, SUFFOLK, BRITISH SUBJECT, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:–

This invention consists of ophthalmic-nutritional preparations for treatment of ophthalmic disorders and in particular for the non-surgical treatment of cataract, treatment of disorders in the ocular media, treatment of glucoma and amblyopia, the treatment of binocular abnormalities including pathological ocular suppression strabismus heterophoria, false-fixation photoreceptor dysfunction low amplitude of accommodation convergence insufficiency, treatment of early presbyopia treatment for removing or reducing early myopia and arresting progressive myopia, treatment of light-intolerance night-blindness ocular headache eye pain asthenopia and treatment of corneal ulceration trachoma conjunctivitis, iritis choroiditis, retinopathy and other infectious eye diseases.

The general effect on the body and its functions of each individual ingredient of the preparations covered by this present invention is of course known, but the effect on the ocular functions and the various structures composing the mechanism of vision of the combination of the various ingredients has only been revealed by the inventors intensive ophthalmic-nutritional research in Africa during the past eight years.

The inventor commenced ophthalmic-nutritional research in the etiology and treatment of the various ocular disorders enumerated above some 25 years ago, but the final preparations covered by the present invention have been evolved during the past eight years in Africa where such conditions or ocular disorders are very much more frequent and occurring in patients of all ages. Having evolved these formulae they have now been thoroughly tested in the eye clinics the inventor established in Africa for a number of years, so that their efficiency is well proved and the preparations now ready for general use.

Full details of the efficiency of such preparations together with clinical case records are being made available through professional ophthalmic publications, as soon as this patent application has been filed.

Nutritional deficiencies in one patient never occur in one nutrient only. There are always parallel nutritional deficiencies, although one deficiency may predominate and give rise to the most outstanding symptom or evidence of nutritional deficiency. For this reason one specific nutritional deficiency may be diagnosed, whilst other nutritional deficiencies may be overlooked. Furthermore, in dealing with the B-Group Vitamins it has been found that when treating an outstanding deficiency in one vitamin of this Group, a deficiency, which did not exist before treatment commenced, of another vitamin of this B-Group is created by administering excessive dosage of the vitamin originally thought to be deficient. Thus it is most essential that when treating any apparent deficiency in a vitamin of the B-Group, any vitamin of this group should not be prescribed in isolation but should be prescribed in combination with all the vitamins of this Group and in the relative proportions in which the body normally requires them, any excess of the vitamin apparently in deficiency being very carefully determined. All these considerations have been carefully taken into account in arriving at the final formulae covered by the present invention so that the preparations basically are suitable for treatment in all the enumerated ocular disorders. In treating specific conditions therefore the basic formula is prescribed combined with additional quantities of specific nutrients according to the necessity of each condition being treated.

Thus in treating evident deficiencies which have been responsible for the ocular disorder a

multiple of the formula may be used which may be combined with additional quantities of specific nutrients, Once the ocular condition has been cured, then the patient will need a considerably reduced dosage to prevent re-occurance of the ocular disorder.

The present invention, therefore, comprises an ophthalmic-nutritional preparation, which together contain the following ingredients in the following relative quantities. A multiple of this basic formula may be prescribed according to the severity of the particular eye condition being treated, and according to the actual nature of that eye condition. In addition the basic formula or a multiple thereof may be combined with additional nutrients and/or minerals. Furthermore, additional quantities of some of the basic nutrients of the formula may be added to the preparation where the condition being treated requires greater quantities of such nutrients or vitamins. For example additional quantities of Vitamin A or Retinol, Vitamin C or ascrobic acid, Vitamin E or ∝ tocopheryl acetate, Vitamin PP or Nicotinic acid may be prescribed with the basic formula. In addition also there may be prescribed other nutrients for increasing the protein intake such as dried yeast, milk and other foods high in protein. Glucose is also frequently prescribed together with these nutrients.

The invention comprises an ophthalmic-nutritional preparation, to be used independent of or in conjunction with orthoptic therapy which may be in tablet form, powder form, capsule form liquid form, as an injectable, suppository or as an eye lotion or eye drop, containing the following nutrients in the following relative quantities per unit dose to be taken together with the patients existing diet, viz.

(a)Vitamin A or Retinol	10,000 to 60,000 international units
(b)Vitamin B_1 or Thiamine	0.5 milligrams
(c)Vitamin B_2 or Riboflavine	0.5 milligrams
(d)Vitamin B_6 or Pyridoxine	0.5 milligrams
(e)Vitamin B_{12} or Cyanocobalamin	0.5 microgram
(f) Vitamin C or ascorbic acid	125 to 2000 milligrams
(g)Vitamin D or Ergocalciferol	1000 internationl units
(h)Vitamin E or ∝ ∝ tocopheryl	25 to 200 milligrams
(i) Vitamin K, Phytomenadione or Menadrol Sodium Diphosphate	1 milligram
(j) Folic Acid	0.5 milligrams
(k)Pantothenic Acid	5.0 milligrams
(l) Niacin or Nicothinic Acid	7.5 to 20 milligrams
(m)Para-Aminobenzoic Acid	10 milligrams
(n)Calcium Lactate,Calcium Glucobeptonate or Calcium Pantothenate	200 to 2000 milligrams
(o)Choline	250 milligrams

As an alternative formula an additional ingredient may be added to the above fifteen nutrients viz.

(p)Inositol	250 milligrams

Furthermore, an alternative calcium salt may be used in addition or in place of ingredient (n) such as calcium glucoheptonate or calcium pantothenate.

As a further modification of the formula the preparation may be made up with the above basic formula but with one or more of the following ingredients reduced or increased as follows:–

(i) Vitamin A may be increased to say 30,000, 50,000 or 60,000 international units. This may depend upon the purpose of the preparation, whether theraputic or preventative. This may also be modified in accordance with the prevailing general deficiency of this nutrient in the basic diets of the peoples being treated.

(ii) Vitamin E may be increased to say 75 mg, 150 mg, 200 mg.

(iii) Vitamin C may be increased to say 1 gram or 2 grams.

(iv) Calcium may be increased to say 1 gram, 2 grams.

(v) The quantity of niacin may be increased to say 10 mg 15 mg 20 mg.

The relationship of the remaining ingredients should however remain substantially as stated above.

Thus the basic formula provides a preparation suitable for prescribing say one tablet or capsule daily as a maintenance dosage for prevention of the various ocular conditions referred to herein on the one hand or for preventing the re-occurance of any such condition after that it has been successfully treated, on the other hand. A multiple of this basic formula, either by making a preparation with a multiple of the stated ingredients or by prescribing more than one tablet or capsule may then be used as a therapeutic dosage for treating any of the said conditions. Some conditions will require more tablets than other conditions, whilst the age of the patient and/or his feeding or other habits will also determine the number of tablets or capsules to prescribe when treating any given condition. This invention is not a complete diet but should be taken together with the patients existing diet.

Ensuring a high intake of protein also materially assists in treatment of cataract and many of the other ocular disorders enumerated above. The protein intake may be increased without materially changing the feeding habits by prescribing dried yeast and/or milk. Glucose is also beneficial in treatment of cataract and other ocular diseases.

It should be noted that in treating any of the stated ocular conditions that in the early stages or onset of a condition there may be a

nutritional deficiency in only a few nutrients, but as the condition progresses additional nutritional deficiencies develop or become evident.

Frequently there co-exists other nutritional deficiencies in the body generally besides those nutritional deficiencies directly responsible for a given ocular condition, and which could act as contributary influences in precipitating onset of the ocular condition. So long as such other nutritional deficiencies exist recovery of the ocular condition under treatment will be hindered and prolonged. A healthy body ensures a much more rapid and satisfactory recovery from any disease or disorder, thus the general condition of the body needs treating simultaneously with treatment of the ocular condition. The present formulae have been evolved with this in mind.

The following examples as to how a single nutritional deficiency may be the predisposing cause of onset of an ocular condition are given.

Over the past 25 years the inventor has carried out intensive research which has revealed that a Vitamin A deficiency is frequently the initial cause of a number of ocular conditions. This basic research has revealed that the function of the ocular muscles is dependent upon the response of the photoreceptors, and that the rods control the functions of the voluntary or extra-ocular muscles, whilst cones not only are responsible for vision but also for the involuntary muscle functions of pupillary contraction and accommodation and basic refraction at infinity.

With regard to the extra ocular muscles which depend upon the response of the rods in the retinae, the rods are surrounded at their outer ends by a substance called visual purple or rhodopsin which is rich in Vitamin A. The function of this substance is to retain the sensitivity of the rods at a substantially uniform level for all levels of illumination. When there exists a Vitamin A deficiency in a patient, there develops a deficiency in dark adaptation. This in turn causes night blindness and light intolerance. Simultaneously with the development of these conditions a deficiency in the fusional reserve functions develop owing to the fact that the voluntary ocular muscles are controlled by the rods, which in turn are controlled by the Vitamin A content of the rhodospin. The depleted fusional reserves interfere with change in fixation and fusion which frequently precipitates onset of pathological ocular suppression. If this condition is allowed to further develop heterophoria and strabismus frequently become evident. With the development of pathological ocular suppression the function of the retinal bipola and ganglion cells is interferred with. If left untreated the dysfunction may extend to the nerve pathways themselves connecting the cells with the cortex. As these conditions progress dysfunction of the different components of the ocular circuits supervene, including those responsible for the onset of heterophoria, strabismus, amblyopia, false fixation, ocular headache, eye pain asthenopia, and photophobia. Such conditions cannot then be cured by administration of Vitamin A alone. Vitamin A must be given in sufficiently large doses to ensure that reserves are fully restored but administration of Vitamin E, Vitamin C and a number of the Vitamin-B-Group nutrients must be made in order to restore normal function of the nerve pathways and other ocular components and to re-establish normal binocular vision. Orthoptic therapy, may also be necessary to stimulate the fusional reserves and remove ocular suppression.

In the case of the development of cataract the inventor's research has shown that in a number of cases of cataract and cloudy media Vitamin A deficiency was the initial cause, or the precipitating cause, although other nutritional deficiencies co-existed. This Vitamin A deficiency depletes the fusional reserves. In order to retain binocular function the internal recti muscles are called into play to compensate for the true fusional convergence (which the inventors research has revealed is a differential function of the vertical recti—superior and inferior rectus—and not a primary function of the horizontal recti—internal recti). As the fusional reserves are depleted there is no longer any flexibility between accommodation and convergence. This in turn causes excessive stimulus of the ciliary muscles, resulting in spasm and congestion of these muscles and the ciliary processes. This in turn restricts the flow of the aqueous humour. When the aqueous humour is already deficient in a number of nutrients consequent upon other general nutritional deficiencies, this restriction in its flow inwards to the crystalline lens interfers with the normal metabolism of the crystalline lens resulting in it losing its normal transparency and thus precipitating the onset of cloudy media or cataract. On the other hand restriction in the outward flow of the aqueous precipitates the onset of glucoma. Thus, as is frequently demonstrated clinically, many cases of cataract and glucoma have a common nutritional cause, and frequently the two conditions are found developing together in the same eye. Thus in treating cataract and glucoma not only is it necessary to provide massive dosage of Vitamin A but also additional nutrients must be supplied to bring the aqueous content up to normal. In addition to restoring the aqueous humour to its normal condition it is necessary that the patients intake of protein should be adequate, as protein deficiency contributes to the development of cataract. Adequate supplies of niacin, Vitamin C and glucose are also necessary. If this is ensured, together with a balanced intake of the Vitamin B-Group nutrients then frequently the opacity of the crystalline lens is removed, the protein of the crystalline lens being changed

and its metabolism corrected thus restoring its transparency.

The development of early presbyopia may also be initially due to Vitamin A deficiency. This is followed by binocular dysfunction, ocular suppression and latent deviation. If this deviation happens to be divergent in character then in order to maintain single binocular vision convergence is inhibited. Owing to the fact that the fusional convergence is depleted as a result of a Vitamin A deficiency, convergence can only be achieved by the primary function of the internal recti muscles working in tandum with ciliary muscles for accommodation. Thus inhibition of convergence by the internal recti is accompanied by inhibition of accommodation, which results in recession of the near point of accommodation or early presbyopia. Thus in treating this condition it is necessary not only to restore the normal Vitamin A balance but also to provide additional nutrients with or without orthoptic therapy for restoring the ocular muscle functions, and nerve pathways controlling them.

In a similar manner this research has shown that the development of myopia is frequently due to depletion of the fusional reserves consequent upon Vitamin A deficiency. Again the internal recti compensate for the true fusional reserves, bringing with them the accommodation. This excessive stimulation of accommodation in turn causes an abnormal development of the growth hormones in the hyperthalmus controlling the length of the eyeball, resulting eventually in abnormal lengthening of the eyeball and producing myopia. There is a lag between the initial stimulus and the final response in the length of the eyeball, so that if treated early a myopia may be reversed, or in medium myopia it may be reduced, whilst in progressive myopia it may be arrested and become stable. Again other nutrients must be prescribed in addition to the original Vitamin A that was deficient and which precipitated the onset of myopia.

In the case of infectious diseases of the eye not only should appropriate eye drops be administered, but in addition a number of nutrients, especially Vitamin A, C and E which promote healing and restoration of nonnal cellular function. In addition the diet should be high in protein. Thus by administering the formulae covered by this invention and supplementating it by additional dosage of Vitamin A, C and E and high protein intake the body is assisted in fighting the infection, and the necessary nutrients are available in sufficient quantities for rapid formation of new cells to replace those destroyed by the disease.

Over the past eight years, by the use of the present invention many cases of cataract have been cured in which previous to treatment the vision had fallen to perception of hand movement only and the fundus reflex was lost. Normal vision with clear media have subsequently been witnessed.

The visual acuity in many cases of glucoma have been substantially increased, whilst many cases of incipient glucoma have been corrected. The danger of the onset of glucoma has been removed in very many cases showing early signs of its onset. Use of a maintenance dosage is a safeguard to onset of both cataract and glucoma.

In the case of binocular abnormalities the use of this formulae has greatly assisted the removal of ocular suppression heterophoria, strabismus, accommodative and convergence deficiences, smarting of the eyes, watering of the eyes ocular headache, and eye pain. Many cases of nightblindness and light intolerance have been cured. Many cases of amblyopia in which the vision had progressively fallen to a very low level necessitating the leading about of the patient, have been completely cured and the vision restored to normal within a few weeks.

Many of the conditions treated with this nutritional therapy are also treated with orthoptic therapy so that the invention also covers the combination of orthoptic therapy with this ophthalmic-nutritional therapy.

In designing the formulae one or more preparations have been produced which are effective in a large number of different eye conditions, and which can be used both as a therapeutic agent as well as a preventative agent.

Having now described the nature of my invention and the manner in which it is to be performed I declare that:

WHAT I CLAIM IS:—

1. An ophthalmic-nutritional preparation to be used independent of or in conjunction with which may be in tablet form, powder form, capsule form, liquid form, as an injectable, suppository or as an eye lotion or eye drop or other pharmaceutical preparation, containing the following nutrients substantially in the following relative quantities, per unit dose, to be taken together with the patients existing diet, viz.

(a) Vitamin A or Retinol	10,000 to 60,000 international units
(b) Vitamin B_1 or Thiamine	0.5 milligrams
(c) Vitamin B_2 or Riboflavine	0.5 milligrams
(d) Vitamin B_6 or Pyridoxine	0.5 milligrams
(e) Vitamin B_{12} or Cyanocobalamin	0.5 microgram
(f) Vitamin C or ascorbic acid	125 to 2000 milligrams
(g) Vitamin D or Ergocalciferol	1000 international units
(h) Vitamin E or α tocopheryl	25 to 200 milligrams
(i) Vitamin K Phytomenadione or Menadrol Sodium Diphosphate	1 milligram
(j) Folic Acid	0.5 milligrams
(k) Pantothenic Acid	5.0 milligrams
(l) Niacin or Nicotinic Acid	7.5 to 20 milligrams

(m)Para-Aminobenzoic Acid	10 milligrams
(n)Calcium Lactate, Calcium Glucoheptonate or Calcium Pantothenate	200 to 2000 milligrams
(o)Choline	250 milligrams.

2. An ophthalmic-nutritional preparation as claimed in claim 1 combined with 250 milligrams of Inositol.

3. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which the quantity of Vitamin A, item (a) is 30,000 international units.

4. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which the quantity of Vitamin A, item (a) is 50,000 international units.

5. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which the quantity of Vitamin A, item (a) is 60,000 international units.

6. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which the quantity of Vitamin C, item (f) is 1 gramme, or 1000 milligrams.

7. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which nutrient (h) Vitamin E is 75 milligrams.

8. An ophthalmic-nutritional preparation as claimed in claim 1 and 2 in which nutrient (n) calcium lactate is 1 gramme or 1000 milligrams.

9. An ophthalmic-nutritional preparation claimed in any of the preceding claims also containing additional nutrients and/or minerals.

10. An ophthalmic-nutritional preparation claimed in any of the preceding claims also containing protein.

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Printed for Her Majesty's Stationery Office, by Croydon Printing Company Limited, Croydon, Surrey, 1976.
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.